

Notice of Allowability

Application No.

10/068,059

Examiner

Mary E. Mosher, Ph.D.

Applicant(s)

MIZZEN ET AL.

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/7/04, 3/10/04.
2. ☒ The allowed claim(s) is/are 1-8,10-17,19-23 and 26-74.
3. ☒ The drawings filed on 05 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 3/10/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 4/28/04
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other Sequence printout.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Upon search of the invention as now claimed, it was determined that a substitution of F for I at core position 97 is one of the characteristic features of the ayw subtype of HBV, see for example SEQ ID NO:2 of Birkett US 6231864 and the attached alignment. However, the ayw subtype sequence has at least one deletion at residues 151-152 when aligned with SEQ ID NO:2, and therefore does not meet the claim limitation of "...comprises the amino acid sequence of SEQ ID NO:2 in which...not more than 25 of the amino acids residues are SUBSTITUTED..." (Emphasis added). The specification clearly indicates that deletions are not substitutions, see page 3, lines 21-22. Therefore, the claim does not read upon simply fusing a conventional ayw subtype core sequence to a stress protein to enhance the immune response against the ayw subtype.

There is one sequence in the prior art which has W at position 97 and lacks the ayw 151-152 deletion, but has a deletion elsewhere in the core sequence, see Gunther et al (Hepatology 24(4), 751-758, 1996), Fig. 10, clone F-2. There is one other sequence in the prior art which has a residue other than I at position 97 and lacks the ayw 151-152 deletion, see the unpublished sequence designated CAA59535; however, there is no particular motivation to choose this sequence out of the myriad of known HBV core sequences for fusion to a stress protein.

Yuan et al (Journal of Virology 73:10122-10128, 1999) teaches that mutation at position 97 is the most frequently observed core mutation, but states a hypothesis that

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the mutation reduces the total infectious titer leading to a decreased level of HBV-specific target antigens, and states that "Whether mutant 97 in general is an immune escape variant remains to be tested experimentally." Again, this does not provide particular motivation to choose position 97 variants for fusion to a stress protein.

Therefore, the invention as now claimed is concluded to be novel and non-obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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7/22/04

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